

Application No.: 10/519,121

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Docket No.: 416272003900

REMARKS

Reconsideration is respectfully requested. The specification has been amended to correct a typographical error. Claim 2 has been amended to correct typographical errors. Claims 1-14 remain pending in the present application.

The specification has been amended to correct a typographical error in an equation presented on page 17. The amendment is supported throughout the application as original filed and at least by the second to last paragraph of page 17 which correctly presents the equation in narrative form. no new subject matter has been added.

Claim 2 has been amended to correct typographical errors. The amendment is supported throughout the application as originally filed and at least by originally filed claim 2.

Entry of the preceding amendments is respectfully requested.

RESTRICTION REQUIREMENT

The Examiner has required restriction between the following groups:

GROUP I - claims 1-14, drawn to a method for determining the rate of reverse cholesterol transport, wherein one or more isotopically labeled high density lipoprotein (HDL) particles are administered to a living system when determining the rate of the first arm of reverse cholesterol transport, and wherein an isotopically labeled bile acid is administered in a different manner than the isotopically labeled high density lipoprotein (HDL) particles when determining the rate of the second arm of reverse cholesterol transport.

GROUP II, claims 1-6 and 10-14, drawn to a method for determining the rate of reverse cholesterol transport, wherein one or more isotopically labeled cholesterol molecules are administered to a living system when determining the rate of the first arm of reverse cholesterol transport, and wherein an isotopically labeled bile acid is administered in a different manner than the isotopically labeled cholesterol molecules when determining the rate of the second arm of reverse cholesterol transport.

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GROUP III, claims 1-6 and 10-14, drawn to a method for determining the rate of reverse cholesterol transport, wherein one or more isotopically labeled cholesterol precursors are administered to a living system when determining the rate of the first arm of reverse cholesterol transport, and wherein an isotopically labeled bile acid is administered in a different manner than the isotopically labeled cholesterol precursors when determining the rate of the second arm of reverse cholesterol transport.

GROUP IV - claims 1-14, drawn to a method for determining the rate of reverse cholesterol transport, wherein one or more isotopically labeled high density lipoprotein (HDL) particles are administered to a living system when determining the rate of the first arm of reverse cholesterol transport, and wherein the isotopic label of the isotopically labeled high density lipoprotein (HDL) particles when determining the rate of the second arm of reverse cholesterol transport.

GROUP V, claims 1-6 and 10-14, drawn to a method for determining the rate of reverse cholesterol transport, wherein one or more isotopically labeled cholesterol molecules are administered to a living system when determining the rate of the first arm of reverse cholesterol transport, and wherein the isotopic label of an isotopically labeled cholesterol molecules when determining the rate of the second arm of reverse cholesterol transport.

GROUP VI, claims 1-6 and 10-14, drawn to a method for determining the rate of reverse cholesterol transport, wherein one or more isotopically labeled cholesterol precursors are administered to a living system when determining the rate of the first arm of reverse cholesterol transport, and wherein the isotopic label of an isotopically labeled bile acid is different than the isotopic label of the isotopically labeled cholesterol precursors when determining the rate of the second arm of reverse cholesterol transport.

Traversal

Applicant respectfully traverses the Restriction and submits that unity of invention exists with respect to Groups I-VI. The Examiner has indicated that lack of unity of invention exists, *a posteriori*, in light of Scheibner et al., as that reference renders obvious or anticipated the technical

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features of the inventions of Groups I-VI. As indicated by the Examiner, Scheibner et al. discloses the technical feature linking Groups I-VI of "administration of isotopically labeled molecules to a living system, and the administration of different types of isotopically labeled molecules in a different manner or with a different label." Applicant respectfully disagrees that this is the only common "special technical feature[s]," within the context of PCT Rule 13.2, to be found in Groups I-VI.

Applicant respectfully asserts that at least step d) ("calculating the rate of dilution... to determine the rate of the first arm of reverse cholesterol transport in the living system"), present in independent claim 1, claims 2-14 which depend from claim 1 and each of the inventions of Groups I-VI, is a special technical feature that "define[s] a contribution, which each of the inventions, considered as a whole, makes over the prior art." PCT Rule 13.2. That the present "calculating" step qualifies as a technical feature is evident from paragraph 10.58 (Example 38) of the PCT International Search and Preliminary Examination Guidelines. In Example 38, the step of "observing the effect of the candidate compounds on ligand binding in a screening assay" was identified as the technical feature of the example claim 1, presented therein. The step of "calculating the rate of dilution... to determine the rate of the first arm of reverse cholesterol transport in the living system" is analogous to the "observing" technical feature step of example 38. Therefore, unity of invention exists, *a priori*, as the "calculating" technical feature is present in each of the inventions of Groups I-VI. Further, Applicant respectfully asserts that unity of invention is still present in Groups I-VI, *a posteriori*, in light of Scheibner et al., as the "calculating" technical step is novel and inventive over the teachings of the reference.

While Scheibner et al. does disclose a method employing the "administration of isotopically labeled molecules to a living system, and the administration of different types of isotopically labeled molecules in a different manner or with a different label," Scheibner et al. does not disclose the key technical feature of "calculating the rate of dilution... to determine the rate of the first arm of reverse cholesterol transport in the living system." As indicated in at least the second paragraph of page 3 and the last paragraph of page 11 of the of the specification, the inventions of Groups I-VI, by virtue of at least the "calculating" technical feature, provide "methods for

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determining reverse cholesterol transport (RCT) *in vivo* by measuring the flow of unlabeled cholesterol from tissues into the bloodstream...instead of the flow of labeled cholesterol." Specification at page 11 (emphasis added). The key technical feature of calculating dilution rates, rather than enrichment rates is clearly a novel and inventive and is a contribution over Scheibner et al., as required by PCT Rule 13.2.

Applicant further submits that under the standard outlined in paragraph 10.04 of the PCT International Search and Preliminary Examination Guidelines, lack of unity of invention should not apply to the present application and that the "the benefit of any doubt [be] given to the applicant." In the present application, Applicant firmly believes that "a single general inventive concept that appears novel and involves inventive step" is present in each of the inventions of Groups I-VI.

Applicant therefore respectfully requests that the present Restriction be withdrawn.

Election

In the event the present Restriction is maintained, Applicant hereby provisionally elects Group II, claims 1-6 and 10-14, with traverse.

In the unlikely event that the transmittal form is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **416272003900**.

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However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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